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| 24113 7590 02/23/2010 PATTERSON, THUENTE, SKAAR & CHRISTENSEN, P.A. 4800 IDS CENTER 80 SOUTH 8TH STREET MINNEAPOLIS, MN 55402-2100 | | | | |
| EXAMINER | | | | |
| KRUSE, DAVID H | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/588,361

Applicant(s)

PRATELLI ET AL.

Examiner

David H. Kruse

Art Unit

1638

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2009 and 10 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,6,7,9-12 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) 16-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,6,7 and 9-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/28/2009
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

STATUS OF THE APPLICATION

1. This Office action is in response to the Amendment and Remarks filed 29 July 2009.
2. The Sentenac Declaration filed under 37 CFR § 1.132 concerning the unintentional error in the sequence listing, and correction thereof is noted by the Examiner. The evidence appears to be sufficient in view of *In re Oda* (see page 23, 1st paragraph of the Remarks). MPEP § 2163(I)(B).
3. The objection to the specification is withdrawn in view of Applicants' amendments.
4. The rejections under 35 U.S.C. § 112, second paragraph, are withdrawn in view of Applicants' amendments to the claims.
5. The rejections under 35 U.S.C. § 102(b) and 103(a) are withdrawn in view of Applicants' correction of the error in the sequence listing.
6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

7. Claims 16-21 remain withdrawn from further consideration pursuant to 37 CFR § 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2 June 2008.
8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one

claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

Information Disclosure Statement

9. The IDS filed 28 September 2009 has been considered with the exception of the Dutruc-Rosset reference on page 1 which was not in English, and Applicants did not provide a summary of the relevant disclosure of said reference. See 37 CFR § 1.98(a)(3).

Claim Rejections - 35 USC § 112

10. Claims 1, 4, 6, 7 and 9-12 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 30 January 2009. Applicant's arguments filed 29 July 2009 have been fully considered but they are not persuasive.

Applicants argue that they have amended claims 1, 6, 7, 11 and 12 to clarify the presently claimed invention to be directed to *Vitis vinifera* vine (page 25, 2nd paragraph of the Remarks). This argument is not found to be persuasive. See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the

description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. At 1406, the court states that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. In the instant case, the limitation "VvSOR" is not art recognized, and does not adequately describe a genus of outward potassium channel encoding genes to which the instant claims are directed. At claim 1, lines 4-5, amending the phrase "an outward potassium channel (VvSOR)" with -- the outward potassium channel encoded by SEQ ID NO: 1 -- would obviate this rejection. Amendment of claims 7, 11 and 12 in a similar manner would also be required.

11. Claims 1, 4, 6, 7 and 9-12 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a plant transformed with and a method of using a nucleotide sequence encoding an outward potassium channel polypeptide that is encoded by SEQ ID NO: 1, does not reasonably provide enablement for a method of modifying the expression of any gene encoding an outward potassium channel. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of

record as set forth in the last Office action mailed 30 January 2009. Applicant's arguments filed 29 July 2009 have been fully considered but they are not persuasive.

Applicants argue that they have amended claims 1, 6, 7, 11 and 12 to clarify the presently claimed invention to be directed to *Vitis vinifera* vine (page 25, 2nd paragraph of the Remarks). This argument is not found to be persuasive. See *Amgen inc. v Chagai Pharmaceutical co.*, 18 USPQ 2d 1016 (Fed. Cir. 1991), which teaches that the conception of a chemical compound requires the inventor to be able to define the compound so as to distinguish it from other materials, and to describe how to obtain it rather than simply defining it solely by its principle biological property; thus, when an inventor of a gene, which is a chemical compound albeit a complex one, is unable to envision detailed constitution of the gene so as to distinguish it from other materials, as well as a method of obtaining it, the conception is not achieved until a reduction to practice has occurred, and until after the gene has been isolated. In addition, it is necessary that the inventor provide a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of the claims, for DNA sequence that means disclosing how to make and use enough sequences to justify grant of the claims sought. In the instant case, the limitation "VvSOR" is not art recognized. It is unclear from Applicants' teachings as to how many outward potassium channel genes there are in *Vitis vinifera*, and which ones would be useful in the claimed methods. Hence, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicants' invention to make and use the invention within the full scope of the claims. At claim 1, lines 4-5, amending the phrase "an outward

potassium channel (VvSOR)" with -- the outward potassium channel encoded by SEQ ID NO: 1 -- would obviate this rejection. Amendment of claims 7, 11 and 12 in a similar manner would also be required.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1, 4, 6, 7 and 9-12 rejected under 35 U.S.C. 103(a) as being unpatentable over Ishitani *et al* (WO 01/45495 A2) in view of Pratelli *et al* (Accession AJ490336, publicly disclosed 11 January 2003, NCBI, National Library of Medicine USA, Bethesda, MD) and in further view of Pratelli *et al* (2002, Plant Physiology 128: 564-577), Gaymard *et al* (1998, Cell 94: 647-655) and Hale (1977, Vitis 16: 9-19).

Ishitani *et al* teach a method of modifying the expression of a gene encoding an potassium channel in one or more cells of a plant including the cells of a storage organ and cells in the tissues supplying the storage organ at claim 23 on page 64. Ishitani *et al* teach said method using a "super promoter" operably linked to said gene at Figure 4. Ishitani *et al* teach the method steps of transforming at least one cell of the plant, selecting the at least one transformed cell and regenerating a transformed plant in Example 10 on pages 55-56. Ishitani *et al* teach use of the CaMV 35S promoter at page 28, 1st paragraph, to express said gene within the whole plant. Hence, the method taught by Ishitani *et al* would overexpress said gene in one or more cells of a plant

including the cells of a storage organ and cells in the tissues supplying the storage organ. Ishitani *et al* teach a method of measuring expression of said gene in tissues supplying a storage organ at Example 17 on page 60. Hence, Ishitani *et al* teach the general level of skill in the art at the time of Applicants' invention to introduce a transgene encoding a potassium channel protein into a plant. Plants comprise many storage organs, such as fruit, roots, tubers, or rhizomes, for example.

Ishitani *et al* do not teach a gene encoding a *Vitis vinifera* outward potassium channel.

Pratelli *et al* (2003) teach a gene encoding a *Vitis vinifera* outward potassium channel expressed in aerial parts of a grape plant.

Pratelli *et al* (2002) teach a nucleotide sequence encoding a *Vitis vinifera* inward potassium channel (see legend for Figure 1 on page 566). Pratelli *et al* teach transformation of a plant using the promoter of the inward potassium channel at page 574, right column, last paragraph.

Gaymard *et al* teach transforming a plant with a gene encoding an outward potassium channel at page 654, left column, 4th paragraph.

Hale teaches that there is a direct relationship between the concentration of potassium in grape berries and the malate and tartrate content thereof (entire document).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicants' invention to modify the teachings of Ishitani *et al* and Gaymard *et al* to use the gene taught by Pratelli *et al* (2003) to transform a grape plant. Ishitani *et al*

teaches that it was obvious to overexpress potassium channel genes in a transgenic plant, and to measure the expression of a gene encoding a potassium channel. Given the teachings of the prior art, one of ordinary skill in the art would have had a reasonable expectation of success.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

/David H Kruse/
Primary Examiner, Art Unit 1638
21 January 2010